



BIOSCIENCE DISCOVERY EVALUATION GRANT PROGRAM
For Early-Stage Bioscience Company Projects
2011-2012 Program
(RULES AND APPLICATION)

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I. PROGRAM OVERVIEW

The Early-Stage Bioscience Company grants under the Bioscience Discovery Evaluation Grant Program (BDEGP) are intended to spur economic development and help new companies born out of Colorado research institutions succeed in developing new technologies, business structures, and product development. Grants up to \$250,000 are accessible to qualified Early-Stage Companies whose technology is licensed from a qualified Research Institution. Grants support the commercialization of bioscience technologies with applications in therapeutic or diagnostic products, devices, or instruments to improve human health; agriculture; or biofuels.

II. APPLICATION AND REVIEW SCHEDULE

OEDIT has established the following application deadline and review/decision schedule:

OEDIT Application Deadline	Grant Decisions
<i>First Cycle:</i> September 30, 2011	November 15, 2011
<i>Second Cycle:</i> January 31, 2012	March 15, 2012

An electronic copy of the application must be received by midnight MST on the deadline date. The application must also be submitted in paper-form, and must include an original signature on the certification page; the paper application may follow the electronic submission.

All funds are available for first cycle applicants; remaining funds will be available in a second cycle. Funds not awarded in these cycles will be available for Early-Stage Company grants in the next fiscal year.

III. STATUTORY AUTHORITY

The Bioscience Discovery Evaluation Grant Program (BDEGP or Program), pursuant to C.R.S. 24-48.5-108 and 12-47.1-701, was established by the Colorado legislature to supply needed resources for improving and accelerating the evaluation process for bioscience research discoveries, to determine the best disposition of these discoveries, and to accelerate viable technologies toward commercialization. The legislature declared that it is in the best interest of the state's economic growth to dedicate financial resources to facilitate the development of new bioscience research discoveries in Colorado and promote Colorado-based bioscience technologies that will ultimately support new bioscience companies and additional primary jobs in Colorado.

IV. ELIGIBILITY

Early-Stage Bioscience Company grants are available to qualified companies that have **licensed a technology from an eligible Research Institution (RI)** or an Office of Technology Transfer (OTT) for the purpose of accelerating the commercialization of:

- A. Therapeutic or diagnostic products, devices, or instruments to improve human health;
- B. Bioscience technologies that improve agriculture; or
- C. Biofuels

Applicants must have **matching funds sourced from grants or third-party investors**; matching funds are **at least equal to the amount applied for under the BDEG program**. The scope of the bioscience project proposed should advance the commercial potential of the underlying technology.

Early-Stage Bioscience Company means a bioscience company that has **received less than \$5 million dollars, for the life of the company, from grants and third-party investors at the time of application**. Third-party investors are defined as non-founders. The company must **employ fewer than twenty people**, and must have its **headquarters in Colorado**.

Research Institution means an institution located and operating in Colorado that is a public or private nonprofit institution of higher education, a nonprofit teaching hospital, or a private, nonprofit medical and research center. For-profit entities are not eligible for the Program.

Office of Technology Transfer means an office that is affiliated with a research institution and that is charged with the responsibility for technology transfer and that arranges for the sale or licensure of a bioscience research project to an outside entity, which is commonly a commercial enterprise.

Qualified Research Institutions and Offices of Technology Transfer are:

Institution	Office	Contact	Phone	e-mail
Bonfils Blood Center	Technology Transfer	Daniel R. Ambruso, MD	303-341-4000	daniel_ambruso@bonfils.org
Colorado Initiative in Molecular Biotechnology	CU Technology Transfer Office	David Allen, PhD	303-735-3711	david.allen@cu.edu
Colorado School of Mines	Technology Transfer	Will Vaughan, PhD	303-384-2555	will.vaughan@is.mines.edu
Colorado State University	CSU Research Foundation Technology Transfer Office	Todd Headley	970-482-2916	todd.headley@colostate.edu
National Jewish Health	Technology Transfer Office	Emmanuel Hilaire, PhD	303-398-1262	hilairee@njhealth.org
St. Mary's Hospital and Medical Center	Western Slope Office of Technology Transfer	Mariah Zerbe	970-243-5242	mzerbe@gjincubator.org
University of Colorado (system-wide)	CU Technology Transfer Office	David Allen, PhD	303-735-3711	david.allen@cu.edu
University of Denver	Intellectual Property and Technology Transfer Office	Carley Pavelka	303-871-4230	cpavelka@du.edu
University of Northern Colorado	Graduate School & Technology Transfer	Robbyn R. Wacker, PhD	970-351-1582	robbyn.wacker@unco.edu

Bioscience Research means the study of biological processes, organisms, devices, diagnostics, or systems with the objective of developing products that are intended to improve agriculture, the quality of human life, or the environment. "Bioscience Research" includes, but is not limited to, biofuel research and life sciences research.

Biofuel Research means the use of microorganisms, specialized proteins, or thermal processes to develop biologically based fuel products from plant matter or other biological material, including renewable agricultural sources, and the related processes that make traditional manufacturing of energy cleaner and more efficient.

V. GRANT AWARDS

The Bioscience Discovery Evaluation Cash Fund has been established to hold monies and provide grant awards for the BDEGP. The Cash Fund is subject to state budget priorities and relies upon funds being appropriated, budgeted, and otherwise made available. The Cash Fund should provide \$1,677,806 for Early-Stage Bioscience Company Grants for fiscal year 2011-12 which includes new appropriations and any funds carried-over from prior years.

A. GRANT MAXIMUM

1. Early-Stage Bioscience Company projects can receive a maximum grant of \$250,000. No early-stage company may receive more than \$250,000 in total grants from the BDEGP including all past grants.
2. The Bioscience Discovery Evaluation Grant Committee (BDEGC) may recommend a grant for an amount other than that requested in the application. Final decisions will be made by the Executive Director of OEDIT.

B. ELIGIBLE COSTS

Costs eligible to be paid under the program may only be incurred after the effective date of a legal agreement executed with OEDIT.

1. Costs should be related to specific time and effort and are readily and specifically identifiable with the bioscience project. Eligible costs include market analysis, clinical development, regulatory and intellectual property costs, business plans, partnering, investor meetings and associated travel. Proposed costs will be reviewed, and may be approved or denied based on BDEGC recommendations. Final decisions will be made by OEDIT's Executive Director.
2. When appropriate, applicants are encouraged to utilize the resources of a qualified business incubator for assistance with structuring and developing their companies. Such costs are eligible for grant funding.
3. Documentation of these expenses, including invoices of actual expenses, shall be maintained.

C. MATCHING FUNDS

Applicants must have matching funds committed at the time of application. At least a 1:1 match of the grant amount requested is required. By project termination, matching funds must be expended on a 1:1 basis. Matching funds must be sourced from other grants or third-party investors; evidence of support from sources outside of the company's principals is an indication of market support for the subject technology and commercialization plan. Matching funds should not be spent prior to BDEGP project approval and execution of a grant agreement.

D. PAYMENTS

Grant participants shall be reimbursed for eligible costs incurred for performance of the project plan. Payments will be disbursed in accordance with the specific terms and conditions of the project and as outlined in the Grant Agreement. OEDIT does not normally advance grant funds for this program.

E. LEGAL AGREEMENTS WITH OEDIT

Grant recipients will need to have an Agreement executed with OEDIT prior to proceeding with any aspect of the bioscience project including the expenditure of state and matching funds.

F. BUDGET ADJUSTMENTS

OEDIT acknowledges that the costs outlined in the Application budget are estimates. Therefore, a Grantee may adjust any budget line-item up to 10% of the total budget without approval from the state. The grantee will need to identify such shifts in its annual project reports. For larger shifts of funds between line-items, the grantee must first seek approval from OEDIT. Please see the sample budget in the *Application* section for an understanding of the budget layout.

G. RETURN OF UNUSED GRANT MONEY

Upon completion of a bioscience project or within 60 days of early-termination of a project by the Grantee's choice, any advanced and unused grant money shall be returned by the Grantee to OEDIT. The funds will be de-obligated and returned to the Bioscience Discovery Evaluation Cash Fund.

VI. APPLICATION REVIEW

A. STAFF REVIEW

OEDIT will review each application against the rules and statutory requirements outlined in this document.

B. BDEGC

1. OEDIT shall convene a Bioscience Discovery Evaluation Grant Committee (BDEGC) comprised of industry experts as well as Colorado Bioscience Association (CBSA) and OEDIT representatives to review, evaluate and make recommendations. All applications will be competitively evaluated by the BDEGC to focus on those that best advance the commercial potential of a bioscience technology. The BDEGC will be interested in the project's potential to strengthen the early-stage bioscience company, attract major capital investment, and to create additional primary jobs in Colorado.

Basic Evaluation Criteria

Sound scientific basis

Clear market potential

Company competitive advantage

Manageable regulatory path

Capable management team

Use of funds will provide a significant return on investment/advancement of the technology

2. The BDEGC operates on a consensus basis. Committee members bring various expertise to the process and rely on one another's input in making recommendations for further consideration and funding. Top applicants will be informed of the BDEGC meeting at which their proposal will be further considered, and are encouraged to attend.
3. OEDIT staff will provide constructive feedback to applicants from the BDEGC as available. Applicant's questions on the review process or feedback should be directed to OEDIT staff. BDEGC members will not discuss committee deliberations with applicants, but may choose to give personal advice.

VII. CONFIDENTIALITY AND OPEN RECORDS

OEDIT is subject to the Colorado Open Records laws (C.R.S. 24-72-101 through 24-72-112). Thus, documents and other materials received by OEDIT and its employees may be subject to public disclosure.

OEDIT will deny the right of inspection of records considered trade secrets, privileged information, and confidential commercial and financial data. Applicants should clearly mark areas of the application they consider to be trade secrets, privileged information, and confidential commercial and financial data. **The entire application may not be marked "confidential"**. Please note that information considered confidential at the time of application may cease to be so at a later date.

Upon receiving an official open records request, OEDIT will immediately notify the applicant and as needed, seek legal guidance from the Office of the Attorney General for a ruling on confidential information. Applicants should be aware that OEDIT can only respond to requests to review records to the extent that such information is contained in OEDIT's files.

The applicant should also be aware that the BDEGC, most of who are not state employees, will receive and review the application documents. Committee members have agreed to lend their expertise and advice in reviewing grant applications, solely to benefit the public. Panel members agree to treat applications and panel discussions as confidential.

VIII. REPORTING REQUIREMENTS

A. ANNUAL PROGRESS REPORT

1. For each project receiving grant funds, the Grantee must submit an annual report documenting the progress of the research and commercialization activity. This report tracks accomplishments related to the objective, obligations and budget developed for each project in the Statement of Work in the Grant Agreement. Grantees will report on results achieved, monetary and other returns associated with developing the technology, intellectual property, and jobs created. The report will need to identify the use of grant and matching funds. A project financial report must be included. A report outline is available from OEDIT. The grantee must complete and return annual reports to OEDIT by March 15th in the same electronic format that the report outline was given. If additional supporting documentation (such as expense receipts) is not available in an electronic format, a hard-copy of the full report and supporting materials should be submitted to OEDIT in addition to the electronic copy of the report.
2. Additionally, OEDIT will request from the OTT from whom the Grantee has licensed the technology, the following information in follow-up reporting on closed or completed projects having received BDEGP grant funds. The follow-up reports will request the following information in order to evaluate the success of the state program in fostering development of Colorado's bioscience industry.
 - Name of project, grant name, grant date, grant amount, total cost of project
 - Status of IP – Was new IP developed? Has the IP been extended or obligated outside of the grantee company? If so, provide details.
 - Follow-on Capital Investment – Since the conclusion of the state Grant Award, what capital investment has this technology received?

B. PROJECT FINAL REPORT

This report is a similar format to the annual report, but is required at the conclusion of a project/grant. The end report should document completion of all activities outlined in the Statement of Work. This report should include an analysis of the results and findings from the project efforts. Technical difficulties, errors, and planned or recommended next steps should be described. A project financial report identifying matching and grant funds must be included. Documentation verifying all project expenditures since the last annual report should be included. An outline for this report is available from OEDIT, and is the same as that for the Annual Report. The final report will be due to OEDIT not later than 30 days before the expiration or sooner termination of a grant (and as identified in the formal Grant Agreement).

IX. AUDITS

A. OFFICIAL AUDIT

Each Grantee will be required to provide a copy of their annual business audit to OEDIT, if an audit is completed and released during the term of the Agreement.

B. PROJECT

OEDIT may choose to audit the business activities performed under the Grant Agreement. A grantee shall maintain a complete file of all records, documents, communications, notes and other written materials or electronic media, files or communications, which pertain in any manner to the activities undertaken pursuant to an executed Agreement. Such books and records shall contain documentation of the participant's pertinent activity under a Grant Agreement in a form consistent with good accounting practice. An Audit Checklist is available from OEDIT.

X. APPLICATION

To be eligible for a grant under the program, a qualified company shall submit to OEDIT (see contact information on page 1) **one original signed hard-copy** application, **and** by **e-mail a Word and/or PDF** file of the application. Such application shall be submitted on or before the OEDIT Application Deadline (see page 2) in order to be considered in an application cycle

The application should follow this format. Please address each statement and answer every question. Presentation and writing are evaluated in the review of the application. Incomplete Applications may not be considered.

Over the 3 years that the program has been open, 49% of applications have been selected for funding. Thirty-eight percent of applicants were awarded a grant in fiscal year 2011. Not all awardees were funded at the level requested.

A. IDENTIFYING INFORMATION

1. Name of Business (include location address, mailing address and website)
2. Key Application Contact (include contact name, phone #, e-mail address)
3. Identify the Business Structure - Check the box describing your business structure and submit the appropriate legal entity structure documentation as applicable:
 - ☐ Sole Proprietorship
Filed Trade/Assumed Name Certificate with the Colorado Department of Revenue.
 - ☐ General Partnership
General Partnership Agreement (no filing required unless the partnership is also operating under a Trade/Assumed Name – if so, follow Sole Proprietorship filing requirements).
 - ☐ Limited Partnership
Filed Certificate of Limited Partnership with the Colorado Secretary of State
 - ☐ Corporation (C or S).
Board Resolution stating who is authorized to incur indebtedness and enter into contracts on behalf of the corporation
Filed Articles of Incorporation with the Colorado Secretary of State, and
Corporate By-Laws.
 - ☐ Limited Liability Company
Filed Articles of Organization with the Secretary of State.
4. Name of Office of Technology Transfer (OTT) & Associated Research Institution (RI) from whom technology was licensed:
5. Has this company or its scientists received any other BDEGP grant? If so, give the BDEGP encumbrance number, dates, and award amount. If the prior BDEGP is not related to the current proposal, give a brief description of the objectives and outcome of that work. If the prior BDEGP grant is related to this current proposal, include information on the objectives and outcomes within the Project Narrative.
6. Check the box(es) that describe the business' area of bioscience:
 - ☐ Human Health - therapeutic or diagnostic products, devices or instruments
 - ☐ Agriculture – bioscience technologies that improve agriculture
 - ☐ Biofuels – development of biologically based fuels
7. Requested Grant Amount (not to exceed \$250,000, excluding matching funds).
8. Provide evidence of the grant match in the form of a commitment letter, grant award notification, verification of deposit, or other document as approved by OEDIT.
9. Indicate the number of people employed by the applicant company.
10. Attach a Capitalization Report – this report will document grant and third-party investor cash injections since the inception of the legal entity. A grant recipient may not have received more than \$5,000,000 from these sources. **Do not include founder capital in this report.**
A founder is one who pursued the idea or technology as a commercial venture prior to any external money being invested or stock being issued. A third-party investor may include such entities as another company, a venture capital firm, "angel" investors, federal, state or local government, or any combinations of the above. It does not include owners of the small business or their direct family members.

The capitalization criterion is relevant at the time of application. Once a company has been awarded a grant, they may increase their capitalization from third-party sources above the qualifying level.

11. Has the business or its principal(s) ever been involved in a bankruptcy or insolvency proceedings?

- Chapter 7 ? No ? Yes Date _____
- Chapter 11 ? No ? Yes Date _____
- Chapter 12 ? No ? Yes Date _____
- Chapter 13 ? No ? Yes Date _____
- Other ? No ? Yes Date _____

If yes to any of the above, please provide an explanation and a description of the current legal status (use a separate attachment for this item).

12. Is the business or its principal(s) involved in any pending lawsuits? If yes, provide a summary.

13. Submit the following Business Financial Information:

- Annual Income Statements for the past 3 years, and a current statement not older than 3 months.
- Balance Sheet covering for the past 3 years, and the current year-to-date not older than 3 months.
- Monthly Cash Flow Projection (including grant project and non-project work) for the anticipated grant term and one year following. Include notes and assumptions.
- Accounts Receivable Ageing Schedule not older than 3 months.
- Accounts Payable Ageing Schedule not older than 3 months.
- Schedule of Outstanding Debt not older than 3 months, detailing term, monthly principal and interest payments, collateral pledged and current status.
- Most recent income tax return.
- Other financial documents may be requested on an as-needed basis.

14. Provide a summary of the license agreement for the subject technology with a qualified research institution or OTT. Include a name or description of the licensed technology, license type, parties involved, and financial terms. *Note: OEDIT will require the RI or OTT to verify this information.*

15. Submit a letter of support from the OTT, including any recommended terms or conditions for consideration by the BDEGC.

16. Include a signed W-9 form.

17. Include a Certificate of Good Standing from the CO Secretary of State.

18. Include a board resolution or company bylaws that identifying the individual(s) authorized to enter into contracts on behalf of the grantee company (please, highlight such information).

19. If applicant is a sole-proprietor, or any individual has greater than 20% ownership if the company, complete a Credit Investigation form.

B. PROJECT NARRATIVE

1. Summary (*1 page or less in layman's terms do not include confidential information*)

Provide a brief summary of the proposed project, including:

- a description of the commercialization plan,
- the scientific research and its merits.
- the current stage of commercialization for the subject technology, along with its anticipated commercial potential.
- identify the market segment that the developed technology will address.
- Will this product/service be a new offering? Does it improve upon existing offerings? Will it partner with existing products/services?

2. Project Technology (3 pages or less).

- Explain the technology, including its scientific basis and research to date.
- Identify and compare competing technologies.

3. Project Plan (3 pages or less in layman's terms).

- a) Describe the specific objectives of the project (*in 70 words or less*). *If approved, this language will become the general description in a Statement of Work.*

- b) Explain how the project or its outcomes will positively impact human health, agriculture, or the biofuels industry. **What market need is being addressed?**
 - c) Describe how the proposed project builds upon previous work that has been conducted by the applicant and other institutions worldwide.
 - d) Identify problems that you might encounter in the proposed project and how you intend to manage and/or resolve them.
 - e) Identify any prior or current grants the applicant has to develop this technology, and explain plans for future grants or other financing for the subject technology.
 - f) Describe how the accomplishment of project goals/milestones will advance the commercialization effort and the company.
4. Commercialization Strategy (2 pages or less in layman's terms)
- a) Explain the market potential for the product or service. Who is your target market? What is your estimated revenue potential?
 - b) Based on the company's stage of development, describe the commercial roadmap (is this an established pathway or must a new model be invented), the product model, business model, revenue model. Provide summary descriptions of comparable products and companies.
 - c) Describe the commercialization spectrum (from infancy to sales) explaining where the technology is today, and how far along the spectrum it will progress by completing the work you plan to undertake with the state grant and matching funds.
 - d) Identify any developed intellectual property to-date on this technology or project. Provide U.S. and International patent and application serial numbers and filing dates as appropriate.
 - e) Specify capital needs, sources, and long-term milestones beyond the proposed project.
 - f) Estimate the long-term outcomes of this project in terms of Colorado jobs and investment.
5. Hazardous Substances
Will project work involve hazardous substances or activities? If so, what precautions are being taken? Note laws that apply, additional insurance, etc.
6. Work Performance Location
Where will project work, including any subcontracts, be performed? List each country and state where work will be performed, and describe the type of work that will be performed at each location.
If it is anticipated that services under the contract, or any subcontracts, will be performed outside of the United States or the State of Colorado, explain why it is necessary or advantageous to go outside the United States or the State of Colorado to perform the contract or any subcontracts.

C. WORK PLAN

Drawing on the Project Narrative, identify project tasks and milestones on a timeline. *Please be concise as these will become the "Obligations" in a Statement of Work.* Make sure to identify project start and end dates in terms of months from an executed Grant Agreement. Be aware that it may take approximately 1.5 months following the grant decision date to process follow-on information and execute a grant agreement. A work plan may include a chart or description of yearly milestones and/or quarterly milestones such as manufacturing, product trials and business plan activities. Examples of business/planning activities could include market analysis, patent activity, securing funds, and regulatory path planning.

D. BUDGET

- 1. Has the subject technology of this application received other grant funding? If so, please provide grant source, amount, and scope of grant project.
- 2. Provide a project budget that supports the Work Plan above. Refer to the Eligible Cost information in the *Grant Awards* section of this document. The budget should include all anticipated project costs and identify Program grant and matching funds. Matching funds must meet or exceed the amount of grant funds requested.

This sample budget outline is provided for direction. Please include a reasonable level of detail for planned project expenditures. Matching funds may be applied to different line-items than BDEGP funds, but should develop the same technology and be spent over the same time period.

<u>Line Item</u>	<u>Source</u>		<u>Total</u>
Project Costs	BDEGP	Match	
Project Management	2,500	2,500	5,000
Incubator Advisory Costs	3,250	3,250	6,500
Clinical Trial Protocol	12,500	12,500	25,000
Regulatory Approval Plan	10,000	10,000	20,000
Market Analysis	4,000	4,000	8,000
IP Assessment & Strategy	12,000	12,000	24,000
Investor Meetings	2,500	2,500	5,000
TOTAL	\$46,750	\$46,750	\$93,500

E. MANAGEMENT TEAM'S BIOGRAPHICAL INFORMATION

Attach curriculum vitae or a short narrative with relevant background and accomplishments for each of the management team and key investigators. Specify relevant company, advisor, and management team capabilities and expertise to execute a business plan.

XI. CERTIFICATIONS

I certify that:

- The bioscience project described in this application and for which the company is requesting Program funds complies with the statutory criteria, rules and application requirements identified in this application document:
 - the project involves the use of biological processes, organisms, devices, diagnostics, or systems with the objective of developing products that are intended to improve agriculture, the quality of human life, or the environment;
 - the scope of the project is the scope required to enhance the commercialization of the technology in Colorado;
- The applicant has a dedicated, matching source of moneys that is equal to or greater than the amount applied for under the Program.
- The information contained in this Application, including all attachments and exhibits, are true and correct.
- The applicant company is headquartered in Colorado. Headquartered is defined as the chief location of a business from which its policies are made and orders are issued.
- The person's or persons' signature on these Certifications and Application are authorized to act on behalf of the applicant company.
- The applicant company will comply with the insurance requirements required for state contracts as found in the model Grant Agreement.

Name and Title

Company Legal Name

Signature

Date

OEDIT reserves the right to modify any of the rules here-in, so long as such modifications meet statutory criteria. Interested parties will be notified of any such modification.